COMPREHENSIVE EVALUATION OF FUNCTIONAL OUTCOMES FOLLOWING TOTAL KNEE ARTHROPLASTY USING INTERNATIONAL CLASSIFICATION OF FUNCTION, DISABILITY AND HEALTH (ICF) MODEL - A LONGITUDINAL CROSS-SECTIONAL STUDY

REGISTER NO: 271710322

A DISSERTATION SUBMITTED TO

THE TAMILNADU Dr. M.G.R MEDICAL UNIVERSITY, CHENNAI,

AS PARTIAL FULFILLMENT OF

THE MASTER OF PHYSIOTHERAPY DEGREE

(ADVANCE PT IN ORTHOPAEDICS)

MAY 2019

CHRISTIAN MEDICAL COLLEGE, VELLORE

TAMIL NADU

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CERTIFICATE

This is to certify that this is the bonafide work of **Mr. C. Sanam Rana** Christian Medical College and Hospital, Vellore, Submitted in partial fulfillment of the requirements for the Master of Physiotherapy Degree course from the Tamil Nadu Dr. M.G.R. Medical University under the Registration No**: 271710322** for the **May 2019** Examination.

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Submitted by

Mr. C. SANAM RANA

Registration No.: 271710322

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- C. Sanam Rana

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ABSTRACT

BACKGROUND: Osteoarthritis is a degenerative change commonly occurs in weight-bearing joints in the hip and knee. Pain and joint stiffness is the common symptoms that gradually leads to muscle weakness and deformity which affects the quality of life. Prevalence of OA knee is increasing due to aging and lifestyle. International classification of function and disability (ICF) is a framework model adapted by world health organization and measures health and disability at both individual and population at large. Implications of ICF give clinicians and researchers a core idea even in the areas of functioning. The ICF model evaluates the individual's ability to participate in the society and the environmental and personal factors that might be a barrier to their participation. Total knee arthroplasty (TKA) is a surgical procedure where the articular surface of the femoral condyle and tibial plateau are replaced with the metal implant. Aim of TKA is to reduce pain, increase range of motion, and improve function. The objective of this study was to evaluate the outcomes following TKA using ICF model.

METHODS: 10 subjects who were planned to be operated for total knee arthroplasty after having met the inclusion criteria were included in the study with a prior consent form. Using ICF model, evaluation of functional outcomes was measured at two different points, at preoperative and followed up at postoperatively at 3 months. Study was approved by an institutional review board, Christian medical college Vellore.

RESULTS: At 3 months postoperative there was a significant change in postoperative outcomes on knee society scores (KSS), muscle power of right hip abductor, WOMAC & LEFS scales, and on two subscales of LLFDI (function component & limitation

subscale of disability component). However, there was no significant change in range of motion, muscle power of quadriceps and left hip abductor, handgrip strength, performance-based measures, and a subscale of LLFDI (frequency subscale of disability component).

CONCLUSION: The study concluded with a need of extensive research using ICF model to provide holistic view of the patient's conditions and plan rehabilitation measures accordingly.

KEYWORDS: OA knee, total knee arthroplasty, and ICF model.

1. INTRODUCTION

Knee osteoarthritis is a common and a major cause of musculoskeletal disorders affecting the quality of life and is the 3rd most disabling conditions with a negative impact on health. (1,2) Osteoarthritis is a degenerative condition of the joint that affects hands, feet, spine and most commonly affects the weight-bearing joints of the lower limb. Hip and knee are the common joints with OA. As the disease progress, there is gradual loss of articular cartilage with joint space narrowing, subchondral sclerosis, and hypertrophy of bone at the marginal ends. (3) In normal knee joint the function of articular cartilage is a shock absorber and it allows free movement and when articular cartilage degenerates it becomes thinner eroded and gradually disappears causing the bone to bone friction leading to pain and mobility impairment. Pain and stiffness leads to muscle weakness and further leads to deformity of the joint that causes severe mobility limitation and further affecting the quality of life. (4)

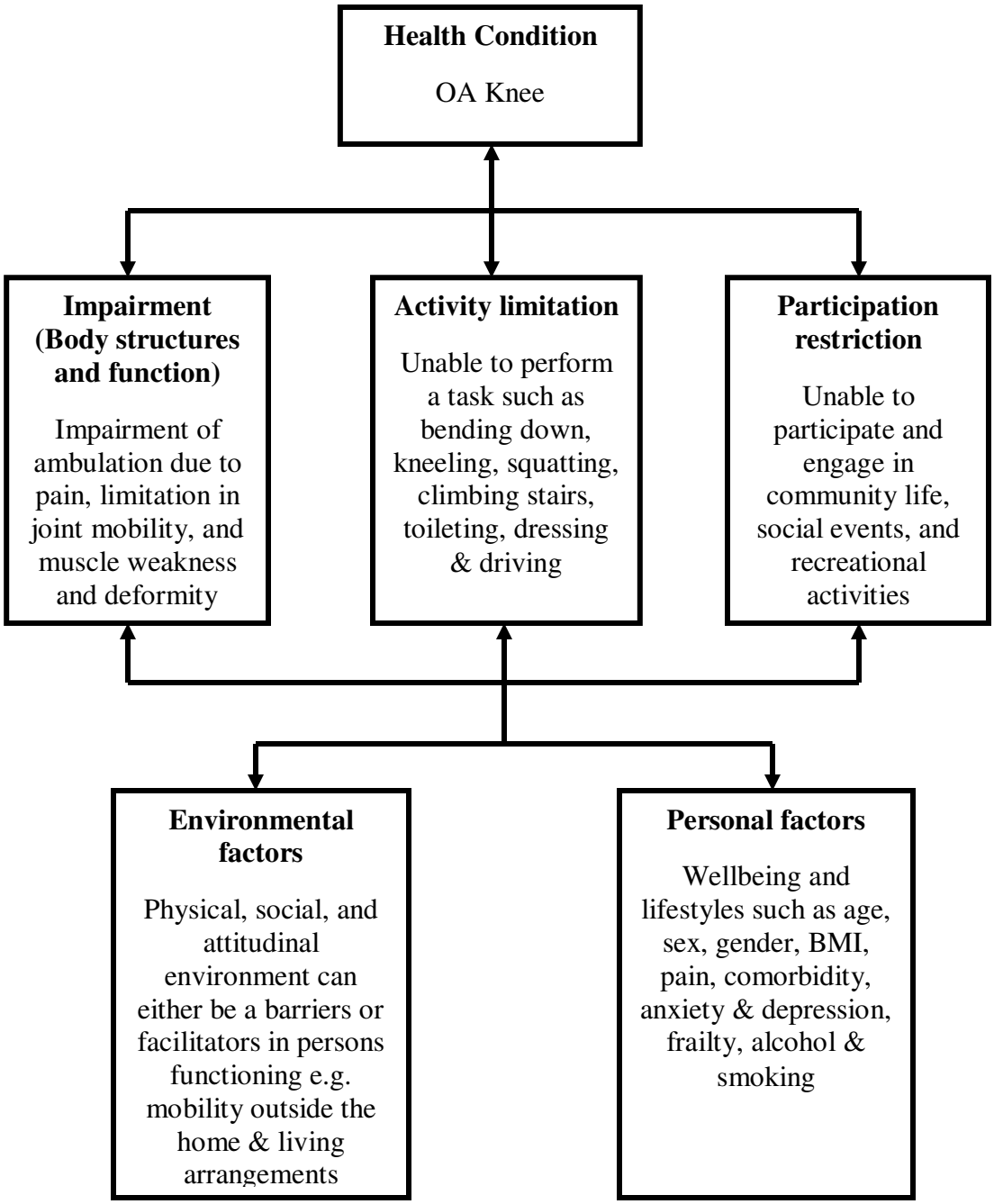
Risk factors associated with OA knee are age, trauma, occupation, exercise, gender & ethnicity, genetics, diet, bone density, and obesity due to a sedentary lifestyle. OA Knee Patients are above 50 years of age and their chief complaint is pain and stiffness which gets aggravated by weight-bearing activities and relieved by rest. (5)

Prevalence of OA knee is higher among Caucasians compared to Asian and black population. (6) Report published in Times of India (2010) about 40 % of Indian population above the age group of 70 years suffers from OA knee of which 2 % of the population has severe pain and disability. (4) Prevalence of OA knee is expected to increase as aging and the rate of obesity increases. (7) Piramal healthcare limited states that India is expected to

be chronic disease capital by 2025 with 60 million people with arthritis. About 80 % of populations with OA knee are having movement limitation, 20 % are not able to do basic activities of daily living and 11 % of the population reports a need of personal care. (4) Prevalence of OA knee in men is lower as compared to females, male with an age of <55 years have a lower incidence of OA knee than females and females with an age of ≥55 years have severe OA knee as compare to males. (8) Diagnosis of OA knee is made based on patient history, physical examination and radiographic examination. (9)

International classification of functioning disability & health (ICF) is a framework model adapted by world health organization (WHO) for describing health-related domains. (10) ICF has 2 components and each component has separate domains. First component is Function and disability and it includes following domains- Impairment i.e. Body structure and function, activity limitation and participation restriction and the second component include contextual factors with a domain of environmental & personal factors. (11)

OA knee classification according to ICF model, impairment component measures knee pain intensity, muscle strength of quadriceps and hip abductors, knee mobility, and hand grip strength. Activity limitation component measures individual ability to walk, bend, sit and stair climbing and Participation restriction component describes individual inability to attend a community and social life such as employment, education, sports and leisure activities. (10,12)



Flowchart: Classification of OA knee based on the ICF model (1)

Total knee arthroplasty is surgical approach performed to relieve joint pain, to correct deformity and improve functional activities. (13) Technological innovation in development of implants has helped in improving joint function and reducing pain. (14) Knee flexion of 110 degrees allows to perform most of the functional activities and that is why most of the knee endoprosthesis is designed to achieve high deep flexion. (15) Femoral component of the knee prosthesis is "J" shaped curve and it comes in contact with the tibial surface. Anterior femoral radius is large and posterior femoral radius is smaller and is designed to allow femoral component into deep flexion to improve function. (16) The number of TKA procedure from 2005 to 2030 is expected to increase by 601 % reaching an estimated of 3.48 million procedures annually. (17)

1.1 NEED FOR STUDY

Previous study on the functional outcomes of TKA have evaluated on one particular aspect of outcomes such as on range of motion or muscle strength or gait kinematics. (18,19) ICF integrates physical, mental, and social aspects of health condition. ICF model incorporates all aspects of person's life on impairment level, activity limitation, and participation restriction, instead of focusing on one particular difficulty. There are limited studies that have evaluated the functional outcomes following total knee arthroplasty comprehensively using ICF model assessment. (REFERENCE) Till date in Indian population there are no studies that have used ICF model in assessment of functional outcomes following total knee arthroplasty.

In this study, we will evaluate and compare the improvements in the functional outcomes of TKA in Indian population using the ICF model comprehensing all the 3 domains- impairment, activity limitation, and participation restriction.

2. AIMS AND OBJECTIVES

AIM: The aim of the study is to comprehensively evaluate the functional outcomes following total knee arthroplasty using ICF model.

OBJECTIVE: To compare the functional outcomes in impairment, activity limitation, participation restriction domains in ICF models following total knee arthroplasty.

HYPOTHESES:

Null Hypothesis: There is no significant difference in functional outcomes based on the ICF model following total knee arthroplasty.

Alternate Hypothesis: There is a significant difference in functional outcomes based on the ICF model following total knee arthroplasty.

3. REVIEW OF LITERATURE

Outcomes of total knee arthroplasty:

Moon et al evaluated and analyzed the clinical and radiological outcome of surgery using Buechel and Pappas (B-P) knee implants. 94 TKA from 60 patients who received B-P knee implant were compared to the results of 60 TKA from 41 patients who received NexGen-LPS knee implants. The American knee society score was used as the outcome measures. Both types of knee implants showed improved outcomes. At 2 years of follow up when compared to NexGen-LPS knee implant, B-P knee implant showed a higher degree of satisfaction in clinical and less intraoperative bone mass removal. (14)

Henderson et al determined that physiotherapy interventions are effective for total knee arthroplasty patients in acute care setting and inpatient rehabilitation in improving pain, range of motion, and reducing the length of stay in the hospital. Studies with RCTs receiving active physiotherapy intervention in the acute hospital or inpatient rehabilitation were included. Risk of bias for individual studies was assessed using physiotherapy evidence database (PEDro) scale. Active physiotherapy intervention reduces the length of hospital stay in acute phase. Few studies showed improved outcomes with hydrotherapy regimes. However technology assisted physiotherapy did not show any difference for activity. (20)

Woolhead et al investigated the experiences of patient outcomes following total knee arthroplasty. 25 patients were included in the study and interviewed before surgery. 15 patients were dropped out and remaining 10 were interviewed at 6 months follow up. Interviewed were conducted by audiotape and transcribed. At 6 months patients were

interviewed about the experience of outcomes and they struggled to make sense of their outcome. Most of the patient reported better outcomes but during discussion they revealed difficult and discomfort in movement of knee joints and experienced persistant pain. Woolhead et al concluded that although TKR gives excellent functional outcomes when using quantitative methods, study may need to be qualified by qualitative findings. (21)

Artz et al evaluated the effectiveness of physiotherapy exercise in patients after primary total knee arthroplasty using systematic review and meta-analysis of RCTs. Outcome measures were assessed by using patient reported pain and function, knee range of motion, and functional performance. 18 trials of total 1,739 patients who underwent TKA were studied. Interventions were compared between physiotherapy exercise, home and outpatient physiotherapy, walking skills, pool & gym-based physiotherapy, and general exercise with and without balance exercises or ergometer cycling. This systematic review and meta- analysis concluded short-term improvement in physical function with physiotherapy exercises however no long term improvement of physiotherapy exercises were identified. (22)

Karnofsky performance scale (KPS):

Vincent Mor et al studied the psychometric properties of Karnofsky performance scale. The Karnofsky Performance Scale (KPS) is use to assess the functional status. It is an observer-rated measure of patient's functional autonomy and ability to participate in normal activities and self-care. Patient's functional status is assess on a scale ranging from 100 (normal activity, no evidence of disease) to 0 (dead). It is completed by the primary investigator through observation and asking brief questions, consistent with

the typical methodology for completing KPS. The inter-rater reliability is found to be 0.97 and the construct validity of the KPS is found to be strongly significant ($P < 0.001$). It has good psychometric properties in people with cancer including good inter rater reliability. Study concluded that KPS is a valuable research tool when applied by trained observers. (23)

Charlson comorbidities index (CCI):

Charlson ME et al the Charlson Comorbidity Index is used to assess the co morbidity load from 19 co-occurring conditions. The Charlson Comorbidity Index is valid across lifespan in adults with cancers. Higher scores indicate higher co morbidity. (24)

Elmallah Randa D.K et al studied prospectively studied the pre-existing comorbidities of 283 TKA patients (172 women, 111 men) using Charlson comorbidity index to identify any factors that affect functional recovery. The effects of CCI on outcomes was evaluated using knee society score (KSS), short form- 36 (SF 36), and lower extremity activity scale (LEAS). Patient with lower CCI scores had significant improvements in KSS at 2 & 5 years follow up and greater improvement in the physical component of SF 36 and higher LEAS score at 2 years follow up. Results from this study showed that patients who had lower CCI scores had greater improvements in pain, activity and functional outcomes following TKA. (25)

Patient health questionnaire (PHQ-9):

Kroenke K et al constructed the patient health questionnaire (PHQ-9) as a self-administered questionnaire to detect the presence and severity of depression. It is used as a diagnostic tool for common mental disorders. PHQ-9 has 9 diagnostic criteria which are based on DSM-4 criteria as "0" (not at all) to "3" (nearly every day). The PHQ-9 is used in cancer patients and has been validated. PHQ-9 is studied on 6000 patients in 8 primary clinics & 7 obstetrics & gynecology clinics. The study concluded PHQ-9 to be a valid and reliable measure of depression severity and hence PHQ-9 is a useful clinical and research tool. (26)

Thekkumpurath et al screened depression in outpatient's cancer subjects. Data were obtained from 4264 patients attending the outpatient cancer center in Edinburgh, UK. All the subjects have completed PHQ-9 to identify major depressive disorder. The PHQ-9 is a 9-item, brief, free-to-use, self administered questionnaire available in most Indian languages. The cut-off score for major depressive disorders is ≥ 8 and should consider as a screening tool for depression in cancer population. (27)

Knee pain intensity using knee society score (KSS):

Nobles PC et al first developed the Knee Society Score (KSS) in 1989 and is widely used even today to evaluate TKA patients, it was later revised into new version in 2011 after adding few more components. A study was done with 101 patients (53-women, 48-men). Statistical and psychometric procedures of subjective and objective data were analyzed and compared to the knee injury and osteoarthritis score and SF-12 scores for

validation. Studies concluded that KSS is a validated tool to measure TKA patients based on surgeon and other clinicians. (28)

Scuderi et al derived the new knee society score from the original knee society score maintaining its integrity. The new Knee Society Score (KSS) is both physician and patient reported scale which can track patient expectations, satisfaction and activity levels. New knee society knee scoring system can be administered preoperatively and postoperatively separately. New KSS is applicable broadly across age, sex, activity level, and implant type. Thus new knee society score is a validated and responsive method for assessing subjective and objective outcomes after total and partial knee arthroplasty. (29)

Knee mobility using standard goniometry:

Jakobsen et al determined the intra-tester and inter-tester reliability of goniometric measurements of active and passive knee joint range of motion administered by the physiotherapists. Knee joint range of motion is evaluated by Goniometer. Active and Passive knee range of motion is measured following TKA was measured in 19 patients. Patient is positioned in supine and measured knee flexion range using a 30 cm standard goniometry by the primary investigator. The knee range of motion assessment using standard goniometry has been found to be reliable when done by the same tester. The minimal clinically significant difference for passive knee range has been cited as 10^{0}. (30)

Muscle strength using Digital force gauge (IMADA):

Schache M B et al studied the effectiveness of targeted hip abductor strengthening following TKA on muscle strength and functional performance. Hip abductor and knee extensor weakness can alter the pattern of gait in individuals having knee OA. Severe knee pain will cause decreased gait speed, reduced stride length and increased time in double support. The above factors will also reduce the activation of hip abductors and knee extensors muscles over a period of time. Early post operative pain is also likely to contribute to the weakness of the hip abductor and knee extensor muscles. Post operatively, weak hip abductor muscles will lead to poor performance during various activities. The Hand held dynamometer (HHD) is a tool to assess strength. It is a reliable and valid tool in measuring strength following total knee arthroplasty. The strength is recorded as kilogram force unit (KGF). (31)

Role of hand grip strength assessment in knee arthroplasty:

Shyam kumar A.J et al studied if hand held dynamometer measurement during preoperative period could predict the post operative length of stay in the hospital following hip and knee arthroplasty. Studies have shown that hand grip dynamometry is a useful screening tool to detect preoperative malnutrition and predict postoperative complications. Hand grip strength is also found to predict mobility in the elderly after major abdominal surgery. 164 patients (male= 64,female=100) undergoing lower limb arthroplasty (83 total knee arthroplasty, 81 total hip arthroplasty) were assessed preoperatively for pinch, power grip and grip endurance using jamar hydraulic dynamometer. The duration of length of hospital stay was recorded for each patient. This

study concluded that the use of hand held dynamometer during preoperative period will help identify patients who are likely to require longer hospital stay following TKA. (32)

Mentiplay et al examined the intra-rater, inter-rater, inter-device reliability, and concurrent validity of rate of force development (RFD) using hand held dynamometer (HHD) for the assessment of isometric strength and power of lower limb. Lafayette analog hand held dynamometer is a well- established instrument to assess isometric grip strength. Intra-rater, Inter-rater, and inter-device reliability of peak force and rate of force development showed good to excellent reliability. Concurrent validity analysis showed moderate to excellent relationships between hand held dynamometer and fixed dynamometry. The reliability and validity of hand held dynamometer (HHD) against fixed dynamometer has been established. (33)

Western ontario Mc Master universities osteoarthritis index (WOMAC):

Salaffi et al postulates that WOMAC is a widely used self-reported questionnaire to evaluate hip and knee arthritis. All WOMAC subscales (pain, stiffness, and physical function) are internally consistent with Cronbach's coefficient alpha of 0.91, 0.81, and 0.84, respectively. The test-retest reliability is satisfactory with ICCs of 0.86, 0.68, and 0.89, respectively. WOMAC is a reliable and valid instrument for evaluating severity of OA knee. (34)

Thumboo J et al studied the reliability and validity of the Western Ontario and McMaster University Osteoarthritis index among the Asian populations with hip and knee osteoarthritis. WOMAC was administered among 66 inpatients and outpatients having hip and knee OA who were seen at a tertiary referral centre in Singapore. The study found with to have good internal consistency (alpha 0.70 to 0.93) and good reliability with intraclass correlations of 0.83 to 0.90. WOMAC is a valid and reliable outcome measure among the Asian population with OA knee. (35)

Lower extremity functional scale (LEFS):

Binkley et al assessed the reliability, construct validity, and sensitivity of Lower Extremity Functional Scale (LEFS). The LEFS was used on 11 adults with lower extremity conditions. This is a self-reported questionnaire with 20 different everyday activities. The total score is 80. Higher scores signify lesser disability. The internal reliability for the LEFS is excellent (α=0.96). The test-retest reliability estimates were R=.86 (95% lower limit CI=.80) for the entire sample (n=98) and R=.94 (95% lower limit CI=.89) for the subset of patients with more chronic conditions (n=31). The scale was reliable and validated against SF-36 and the sensitivity was superior compared to SF-36. The MCID for LEFS is 9 points. Thus LEFS is efficient to administer in clinical decision making and research purposes. (36)

Yeung Teresa S.M et al studied the test-retest reliability, construct validity, and responsiveness of the LEFS on the inpatients admitted to orthopedic rehabilitation ward. 142 Orthopedic inpatients completed the self reported questionnaire of LEFS on admission, 7-10 days after admission, and on discharge. The study concluded that the

lower extremity functional scale is reliable, valid with large responsiveness among patients admitted in the orthopedic ward. (37)

Six minute walk test:

Kennedy DM et al examined the reliability and sensitivity of six minute walk test in patients with hip or knee OA who underwent total joint arthroplasty. Six Minute walk test (6MWT) is a sub-maximal exercise test used to assesses aerobic capacity & walking endurance. It is an important functional testing measure in assessing the outcomes after total knee arthroplasty, especially in the early postoperative period. 6 MWT produce greater responsiveness in this study. The test-retest reliability of 6 MWT in osteoarthritis has been established as excellent (ICC=0.94). The minimal clinical important difference (MCID) established for TKA patients is 26 to 55 meters. (38)

Jakobsen TL et al assessed the reliability of six minute walk test in patients who underwent recent TKA. 6MWT has been proved to be reliable in TKA, ICC 2=0.97, SEM=13.0, Smallest Real Difference (SRD) =336.1 meters. 6-minute walk test is a functional performance test that measures a person's ablity to walk maximum distance in 6 minutes. The intra-tester reliability of 6 MWT was high in patients with TKA. This study recommends that the longest distance walked in 2 supervised test trials should be used. (39)

30-second chair stand test (30 CST):

Unver B et al investigated the reliability of 30-second chair stand test in patients who have undergone TKA. 30 second chair stand test is a functional test of lower limb strength and endurance in TKA patients. 30 CST is a measurement that assesses

balance - Non vestibular, functional mobility & strength in older adults. This test is used in Arthritis and Joint conditions. Studies find 30 CST to be excellent reliable in patients with TKA. 30 CST is found to be useful in research and clinical practice. (40)

Jones et al investigated the Test-retest reliability and the criterion-related and construct validity of 30 second chair stand test in adults above 60 years. Test-retest intraclass correlations of 30 CST has good reliability. Criterion-related validity of 30 CST has a moderately high correlation between chair-stand performance and maximum weight-adjusted leg-press performance. Performance of chair-stand have decreased significantly across age group in decades from the 60s to 80s ($p<.01$) and was lower significantly for low-active participants ($p<.0001$). Study concluded that 30 second chair stand test is found to be reasonably reliable and valid indicator among older adults. (41)

Stair-climb test:

Whitchelo et al synthesized the available evidence for the factors affecting stair climbing in patients with OA knee before and after TKA. Stair Climbing Test (SCT) is an important measure of functional capacity following TKA. One of the most challenging activities in persons with osteoarthritis is ability to negotiate stairs. Thirteen studies were included in this review - 9 studies investigated OA knee population and 4 studies investigated TKA population. Stair climbing ability was greater in OA knee patients due to stronger lower limb muscles and less knee pain. For TKA patients there was less evidence. (42)

Almeida GJ et al determined the inter-rater reliability and measurement error of stair climb (ascend/descend - total stairs of 11) to find the evidence as valid measures of

physical function. Stair climb test measures the strength of lower limb, balance, and agility through ascending and descending a flight of stairs. Finally 22 subjects with unilateral TKA were analyzed. The intra-class correlation coefficient was 0.94, standard error of measurements were 2.6 sec. The patient reported measures of physical function have small correlation with stair climb test. Hence stair test is not associated with psychological factors and knee extension range but it is associated with knee flexion range. Studies conclude that stair climb test has good inter-reliability for clinical use among patient with TKA. (43)

Time up and Go test:

Steffen et al determined the fall risk and measured the progress of balance in sit to stand and walking. This test is intended to be done in the elderly population but is used for people who have undergone TKA. TUG is the total time to rise from chair, walk 3 meters, turn around, return to chair and sit down. Lower value is better performance. Inter rater and intra rater reliability has been found to be high 0.92-0.99. The construct validity has been shown by correlating TUG scores with gait speed (Pearson r = .75), postural sway (Pearson r = -.48), step length (Pearson r = -.74), Barthel Index (Pearson r = -.79), and step frequency (Pearson r = -.59). (44)

Yeung Teresa S.M et al examined the test-retest reliability and validity of the time up and go test for measuring change and predicting the legth of stay in an inpatient orthopaedic rehabilitation ward. The test-retest reliability and validity of time up and go test was analyzed in 142 orthopedic inpatients and concluded with the good relative reliability of intraclass correlation coefficient of 0.80. Thus this study concluded TUG test

to be reliable and valid to assess group change of inpatients but not a good predictior of length of hospital stay. (45)

Late-life Function and Disability Instrument (LLFDI):

The Late life function and disability index is a general measure of physical disablement developed for older adults by **Beauchamp et al**. It can also be used across a wide range of health conditions. The 2 components of LLFDI measure the function and disability. The function component is measured as a separate subscale related to upper-extremity function (e.g., holding a glass of water, using utensils, unscrewing a lid), basic lower-extremity function (e.g., getting in/out of a car, bending over while standing, walking around the home). The disability component items measures frequency and limitations in activities have subscales for social (e.g., go out to public places, visit friends) and personal roles (e.g., errands, household business). The test–retest reliability for the LLFDI function component was very good (0.81–0.96) and inter rater reliability was found to be very good (0.62– 0.96). (46)

Sayers Stephen P et al assessed the concurrent and predictive validity of the late-life function and disability instrument. 101 men and women were participated in the study. Performance based test for lower extremity function was measured by the Short Physical Performance Battery (SPPB) and a self paced 400 m walk test. Self reported function and physical disability was measured by LLFDI. Study supports LLFDI scales as a substitute for performance based test when self report is a preferred data collection format. The study concluded LLFDI to be a valid tool for both the functions and disability component. (47)

4. METHODOLOGY

4.1 STUDY DESIGN: A longitudinal cross-sectional observational study

4.2 STUDY POPULATION: Patients with unilateral total knee arthroplasty (4 Male & 6 Female)

4.3 STUDY SETTING: Physiotherapy unit, Department of Physical medicine and rehabilitation, Christian medical college and hospital, Vellore

4.4 STUDY DURATION: 1 year

4.5 SAMPLE SIZE: 10 participants

4.6 SAMPLING TECHNIQUE: Convenient sampling technique

4.7 CRITERIA FOR SELECTION

Inclusion criteria

a) Patients admitted for total knee arthroplasty with a diagnosis of osteoarthritis or post-traumatic arthritis

b) TKA using single radius or multi-radius implant

c) Both gender

Exclusion criteria

a) Simultaneous bilateral total knee arthroplasty

b) Revision total knee arthroplasty

c) Compromised bone stock requiring metallic augments

d) Diagnosis of either rheumatoid arthritis or systemic lupus arthritis

4.8 VARIABLES:

Dependent variables

a) Knee pain

b) Knee ROM- Flexion & Extension

c) Knee Extensors & Hip Abductors muscle strength

d) Hand Grip strength

e) 30-second chair stand test (30CST)

f) Stair climb test (SCT)

g) 6-minute walk test (6MWT)

h) Time up & Go Test (TUG)

Independent variables

a) Age

b) Gender

c) BMI

d) Obesity

e) Surgical fitness (ASA classification)

4.9 OUTCOME MEASURES:

- **Pre evaluation screening**

1. Karnofsky performance scale (KPS) measures functional impairment
2. Charlson co morbidity index (CCI) categorize different co morbidities
3. Patient health questionnaire (PHQ 9) measures the symptoms of depression

- **Physical impairment**

1. Knee society score (KSS) measures knee pain intensity
2. Goniometry measures knee ROM
3. Digital force gauge (IMADA) to measures hip and knee muscle strength
4. Lafayette analog hand held dynamometer to measures hand grip strength

- **Activity limitation**

Patient-reported activity limitation measures by

1. Western Ontario and McMaster University Osteoarthritis Index (WOMAC)
2. Lower Extremity Functional Scale (LEFS)

Performance-based activity limitation measures by

1. 30-second chair-stand test (30CST)
2. Stair climb test (SCT)
3. 6-minute walk test (6MWT)
4. Time up and go test (TUG)

- **Participation restriction**

1. Late life function and disability instrument (LLFDI) measures participation restriction on function and disability component

4.10 TOOLS & MATERIALS:

1) Universal standard Goniometry to measure Range of Motion

2) Lafayette analog Hand he0ld Dynamometer to measure Grip strength

3) Digital force gauge (IMADA) to measure the strength of Hip & Knee

4.11 PROCEDURE OF THE STUDY

The study was designed as a longitudinal cross-sectional study evaluated preoperatively and postoperatively at 3 months. The study was chosen to see the difference in the functional outcomes using ICF model in total knee arthroplasty. The study was approved by an institutional review board and ethics committee, Christian medical college Vellore (IRB Min. No. 11215 [OBSERV] dated 05.03.2018).

10 patients (age 45 to 73 years) planned for unilateral total knee arthroplasty who fulfilled the inclusion criteria were included in the study. Patients were recruited from the Department of Orthopedic Unit-3, CMC Vellore. Patients with both genders having diagnosed with osteoarthritis were screened for eligibility and the informed consent was obtained before the collection of data and participation form in the language of their preference.

Pre-evaluation screening of functional status, co morbidities and depression were evaluated pre and postoperatively. Functional status was measured by using Karnofsky performance scale (KPS), co morbidities was measured by using Charlson co morbidity index and Depression was measured by using PHQ-9 scale.

All the patients were evaluated at two different points in preoperative and postoperative at 3 months on three health-related domains of ICF model- impairment, activity limitation and participation restriction.

Impairment domain measures intensity of knee pain using knee society score, knee mobility using standard goniometry. The knee and hip muscle strength of quadriceps and

gluteus medius (ipsilateral and contralateral) was measured using digital force gauge (IMADA). The hand grip strength was measured using Lafayette's handheld dynamometer.

The limitation of activity was evaluated based on two outcome measures - patient reported activity limitation and performance-based activity limitation. The patient-reported activity limitation was measured by using WOMAC (Western Ontario and McMaster university osteoarthritis index) and LEFS (Lower Extremity Functional Scale).

The performance-based activity limitation was measured by doing 30-seconds chair stand test, stair climb test, six-minute walk test & timed up and go test. A participation restriction was measured by using LLFDI (late life function and disability instrument).

Surgical data was obtained from electronic medical records that include OA staging (kellgren Lawrence grade), surgical approach, fixation technique, prosthesis type and American Society of Anesthesiologists (ASA) classification.

Outcome measures:

Pre-evaluation screening:

Pre-evaluation screening was evaluated at preoperative and it included 3 scales i.e. Karnofsky performance scale, Charlson comorbidity index, and patient health questionnaire - 9. Pre-evaluation screening was measured to find the influence and prognosis on functional outcomes following total knee arthroplasty.

- Karnofsky performance scale

KPS was used to evaluate the functional impairment. A loss of function could be either due to physical, physiological, and psychological effects of disease. KPS is a clinician reported questionnaire completed by the clinician and therapist. KPS has 11 questions and each question is score from 100 to 0, where 100 indicate normal functioning and 0 indicates dead.

- Charlson comorbidity index

CCI is a scale that categorizes comorbidities of the individual subjects. According to the risk of mortality each of the comorbidity has an associated weight from 1 to 6. CCI is a clinician reported questionnaire completed by the clinician/therapist. The subjects will be given a single comorbidity score based on the total number of comorbidities. '0' indicates subject is free from comorbidities. Higher the score greater is the risk with the predictive outcome of mortality.

- Patient health questionnaire 9

PHQ 9 is a self-administered questionnaire used to measure the symptoms of depression. PHQ 9 has 9 items to evaluate and each item is scored from 0 to 3. '0' indicates level of depression (not at all) and 3 indicate (nearly every day). The PHQ 9 score ranges from 0 to 27. A score of 5 indicates mild depression, 10 indicate moderate depression, 15 indicate moderately severe depression and more than 20 indicates severe depression.

<u>Preoperative and postoperative evaluation at 3 months:</u>

Pre operative and post operative evaluation was completed by the primary investigator using the standard procedure.

- Impairment:

Knee pain intensity was recorded by asking the patient to verbally rate pain from mild, moderate and severe and marked on the pain score of knee society scale (KSS).

Knee range of motion was measured by a standard goniometry of 30 cm with the patient in supine lying. The standard goniometry using lateral femoral condyle as axis and greater trochanter as the reference point was employed. The participants were asked to flex the knee to the maximum range possible without lifting the foot. The range is evaluated two times and the best range is recorded.

Muscle strength of hip abductor and knee extensor muscle was measured by digital force guage (IMADA). The quadriceps strength was measured with the patient in high sitting position and the knee flex at 90 degree. The digital force gauge was held against the distal end of the leg above the ankle joint by the primary investigator. The participants were instructed to extend the knee against maximal isometric resistance and held for 5 seconds. Similarly for Gluteus medius strength the patient was positioned at the edge of the bed in supine lying and the digital force gauge was placed 5 cm proximal to the lateral femoral condyle. The participant was instructed to exert maximum abduction against resistance and held for 5 seconds. Three trials were done with 2 minutes rest in between. The best of the three trials was considered for analysis.

Hand grip strength was measured using Lafayette analog hand held dynamometer. The dominant hand was used to evaluate the hand grip strength. Participants were seated with arms rested on the arm rest of the chair. The elbow was flexed to 90 degree and forearm in neutral position, and the participants had to maximally grip the dynamometer for 5

seconds. Two trials were performed with at least 3 minutes rest in between. The average of both the trials was taken for analysis and recorded in kilogram force unit.

- Activity limitation:

Activity limitation was measured using two methods - patient reported outcome measure and performance based outcome measure.

a) Patient-reported outcome was measured using two scales, Western Ontario and McMaster University Osteoarthritis Index (WOMAC) and Lower Extremity Functional Scale (LEFS). The partcipants were instructed to complete both the questionnaires.

- **Western Ontario and McMaster University osteoarthritis index (WOMAC)**-

WOMAC is a self-reported questionnaire used for health-related outcomes of OA knee assessing pain, stiffness, and function. The questionnaire has 24 components divided into 3 domains- pain (5 items), stiffness (2 items) and physical function (17 items) with a score range for Pain (0-20), stiffness (0-8) and physical function (0-68). Questions are graded based on a 5 point Likert scale from 0-4, where 0 is (None), 1 (mild), 2 (Moderate), 3 (severe) and 4 (extreme). Sum of all the 3 domains scores gives the total score of WOMAC. Higher scores indicate the worst pain, stiffness and physical limitations. The time taken to administer the scale was 12 minutes.

- **Lower extremity functional scale (LEFS)**-

LEFS is a well-known and validated instrument for measurement of lower extremity musculoskeletal conditions or disorders. It is used to measure the initial function, ongoing progress and outcomes. LEFS is a self-report questionnaire with 20 items having a score

from 0 to 4 where 0 is (extreme difficulty or unable to perform the activity), 1 (quite a bit of difficulty), 2 (moderate difficulty), 3 (a little bit of difficulty), 4 (no difficulty). Total score range is from 0-80, a higher score indicates high function and lower scores indicates very low function. The time to administer the scale was 5 minutes.

b) Performance-based activity limitation

Performance-based activity limitation is a set of functional task which measures balance, agility, endurance, lower body strength, and ascending & descending stairs. Four performance based scales were used to measures the functional task before and after TKR.

- **30-second chair stand test-**

The 30CST was done to measure the strength, balance and endurance of the lower limb. It measures the number of repetitions rising up from chair in 30 seconds. Partcipants were made to sit on a chair with no arm rests and backed against wall to prevent slipping. Both arms were crossed on the opposite shoulder at the wrist. A stopwatch was used to measure the time to complete the test. The test started on the command of "Go", and the stopwatch was started simulataneously. Participants had to stand from the chair fully extended and sit back. The number of repetitions the patient performed this activity in 30 seconds was taken as the final score. The use of arms to push off or incomplete stands was not counted. If patient could not complete the test the score was recorded as zero. More repetitions in 30 seconds signified a better performance.

- **Stair climb test-**

The stair climb test was done to measures the ability to ascend and descend a flight of 10 stairs (14 cm height and 33 cm depth). Prior to the test, the partcipants were instructed about the test and asked to complete the test in their own pace. The participants were told to use the handrail on one side if they found it difficult to negotiate stairs without support. The participants who felt unsafe to climb stairs without mobility devices were allowed to use a walking stick. A stopwatch was used to measure the time to complete the test. The test started on the command of "Go", and the stopwatch was started simultaneously. Participants ascended the stairs, turned around and descended back and stopped with both feet landing back on the ground. The stopwatch was stopped and the time taken to complete the test was recorded. The outcome was measured in seconds. Lower value indicated better performance.

- **6-minute walk test-**

The 6-minute walk test was done to measure the aerobic endurance capacity. The distance covered over a period of 6 minutes was used as the outcome to compare changes in performance capacity. Before and after this test, the vital parameters - Heart Rate, Blood pressure, SPO2, and distance walked were recorded. The participants were advised to do the best as possible but not push to the point of overexertion. A stopwatch was used to measure the time to complete the test. Walking aids were allowed to be used if required. Participants were instructed to stand with both feet on the start line marked on a corridor at '0' meter. The test started on the command of "Go", and the stopwatch was started simultaneously. Participants walked upto 15 meters in normal pace of walking, turned

around and walked back to start line and continued walking upto 6 minutes. Rest period was allowed but included in the time (stop watch was not stopped during the course of test). Stopwatch was stopped at 6 minutes and the total distance walked was calculated in meters. Outcome measured was the distance walked in meters during the 6 minutes. The greater distance walked better the performance. (Figure 1)

Figure 1: Patient performing 6 minute walk test

- **Time up and go test (TUG)**

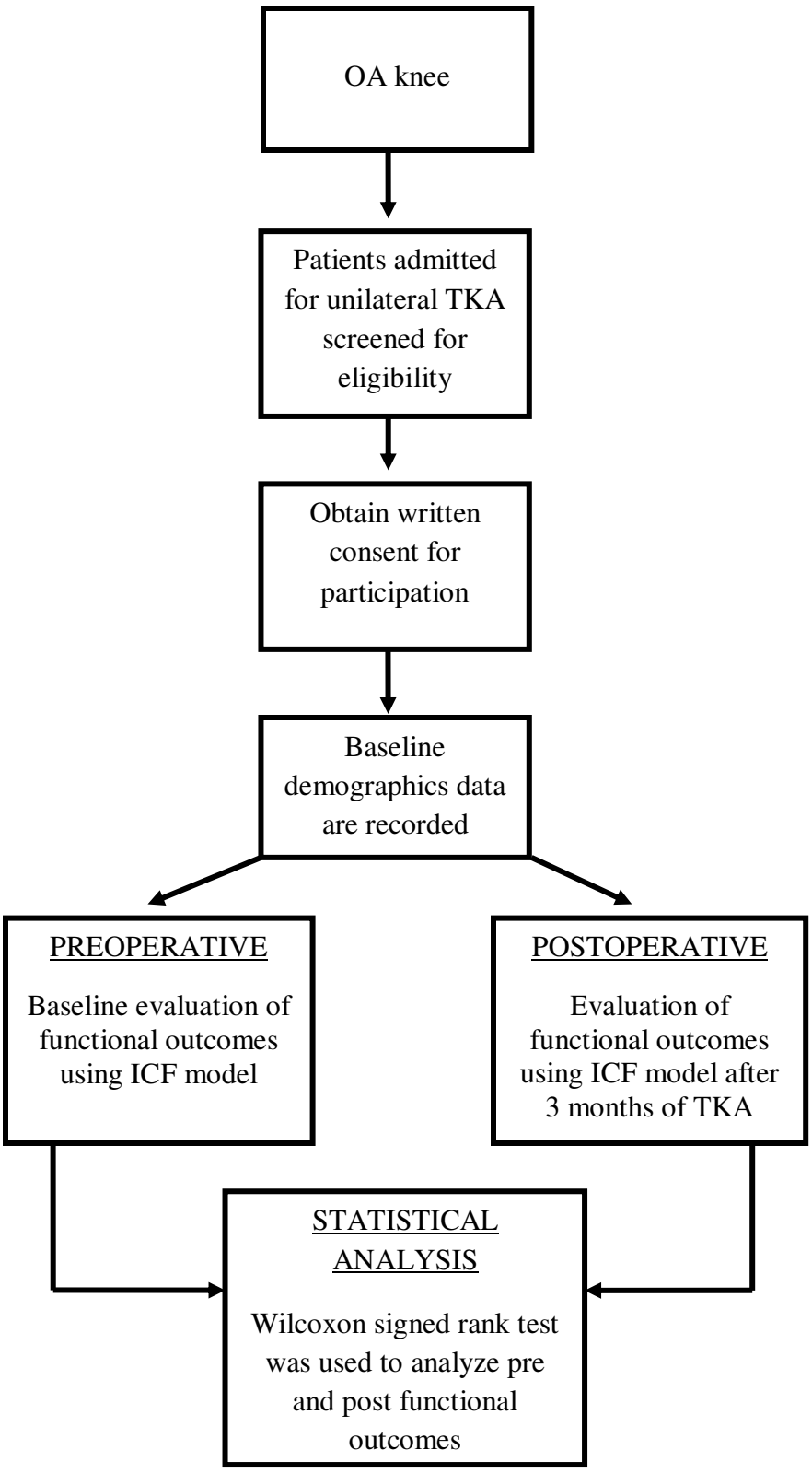
The TUG test was done to measure mobility, static, and dynamic balance. TUG is the total time to rise from chair, walk 3 meter, turn around, return to chair and sit down. The participants was instructed to sit on an armchair with the seat height of 17 inches and back supported on the backrest. Chair was kept against the wall to prevent sliding during the test and walking aid was allowed to be used if necessary. A stopwatch was used to measure the time to complete the test. The test starts on the command of "Go", and the stopwatch was started, patient rise from the chair and walked 3 meters marked on a corridor in a normal pace and return back to the chair and sit. The participants were advised to take the support of armrest if necessary. Stopwatch was stopped once the patients sit back with complete back support. Outcome was measured in seconds. Lower value better performance.

- <u>Participation Restriction</u>

Participation restriction was measured using a scale known as Late-life function and disability instrument (LLFDI). LLFDI is patient-reported outcome measure (PROs) that is designed to assess function and disability. The participants were instructed to complete the questionnaires. On the functional component it measures an individual inability to perform task and disability component measures an individual inability to participate in community or social life. The functional component has 32 questions on physical tasks with 3 subscales- basic lower extremity, advanced lower extremity, and upper extremity. Disability component has 16 major life activities that measure limitations and frequency of taking part in the community and social life. Limitation dimension has 2 subscales- instrumental and management role. Frequency dimension includes 2 subscales- social &

personal role. Raw scores which patient obtained is transformed to scaled scores (0-100). Higher scores indicate better functions.

4.12 ALGORITHM:



4.13 STATISTICAL TOOLS:

Data were analyzed using SPSS version 20. Due to small number of observations and not following the normality of data, functional outcomes between preoperative and postoperative TKA was analyzed using Wilcoxon signed rank test. Categorical data were reported in frequency and percentage.

Wilcoxon signed rank test is a non parametric hypothesis test to see if the medians of two distributions are the same, before-after differences exist.

H_0: The median differences is equal to zero

H_1: The median differences is not equal to zero

Level of significance: 5%

Test statistic:

$$z = \frac{T - \frac{n(n+1)}{4}}{\sqrt{\frac{n(n+1)(2n+1)}{24}}}$$

T_+ = Sum of the ranks of the positive differences

T_- = Sum of the ranks of the negative differences

Test Statistic = Smaller of T_+ & T_-

5. RESULTS

Table 1

Descriptive statistics:

	Mean (SD)
Age	59.20 (8.16)
BMI	28.79 (4.77)
Length of stay	10.40 (2.22)
Karnofsky performance scale	78.00 (7.88)
Charlson co morbidity index	1.40 (1.35)
PHQ-9	7.00 (3.91)

Table 1 shows descriptive data that was used to summarize the preoperative characteristics of subjects. Mean age of subjects were 59.20 (SD±8.16), mean BMI of all subjects were 28.79 (SD±4.77), and mean length of hospital stay were 10.40 (SD±2.22). Mean value of Karnofsky scale, Charlson co morbidity index and PHQ-9 were 78.00 (SD±7.88), 1.40 (SD±1.35), and 7.00 (SD±3.91) respectively.

Table 2

Patient demographic parameters:

Parameters		Frequency	Percentage
Gender	Male	4	40
	Female	6	60
Diagnosis	OA knee B/L	4	40
	OA knee Right	2	20
	OA knee Left	4	40
Education	Primary	1	10
	Middle	1	10
	Secondary	3	30
	Higher Sec	2	20
	Diploma	1	10
	Graduate	2	20
OA staging (kellgren Lawrence scale)	Moderate	4	40
	Severe	6	60
Operating knee	Right	4	40
	Left	6	60
Fixation technique	Cemented	10	10
ASA classification	Normal healthy patient	1	10
	Mild systemic Disease	9	90

Table 2 shows patient demographics with female more than male in the study (M=40%, F=60%). 4 subjects were diagnosed with left OA knee and B/L OA knee respectively and 2 subjects diagnosed with right OA knee (OA knee_L 40%, OA knee_B/L 40 %, & OA knee_R 20%). On education only 2 subjects were graduate and rest education level were diploma, higher secondary, secondary, middle and primary. 6 subjects got operated on the left knee and 4 subjects got operated on the right knee (TKA_L= 6, TKA_R=4). All the subjects received similar fixation technique (100%). Based on ASA classification 1 subjects was found to be in normal health and rest 9 subjects were having mild systemic disease (ASA_N= 10%, ASA_M= 90%).

Table 3

Co-morbidities:

Variables	Yes (%)	No (%)
Hypertension	4 (40%)	6 (60%)
Diabetes	5 (50%)	5 (50%)
Obesity	1 (10%)	9 (90%)
Hypothyroidism	1 (10%)	9 (90%)
Ca mastectomy	1 (10%)	9 (90%)
Renal transplant	1 (10%)	9 (90%)
Bronchial asthma	1 (10%)	9 (90%)

Table 3 shows the coexistence of various co-morbidities on each subject. Among all co-morbidities hypertension and diabetes were found common. 4 subjects have hypertension

and 5 subjects have diabetes and 1 subject each was found to have obesity, hypothyroidism, Ca mastectomy, renal transplant, and bronchial asthma.

Table 4

Comparison of Pre and Post operative functional outcomes on ICF (impairment):

Variables	Preoperative Median (IQR P25,P75)	Postoperative Median (IQR P25,P75)	p value
KSS_KS	43.5 (37.5,50.25)	74 (70,80)	0.002*
KSS_FS	40 (40,48.75)	80 (72.5,87.5)	0.021*
KSS_TS	82 (76.25,92.25)	142 (131.75,157.75)	0.002*
Knee Flexion ROM_R	130 (120,133.75)	127.5 (125,130)	0.125
Knee Flexion ROM_L	115(11.25,123.75)	107.5 (85,123.75)	0.726
Knee Extension ROM_R	0	0	0.500
Knee Extension ROM_L	0	0	0.500
Knee Extensor Muscle Strength _R	9.885 (7.77,14.39)	9.46 (5.32,12.25)	0.215
Knee Extensor Muscle Strength _L	9.355 (4.90,13.26)	9.165 (5.79,12.07)	0.109
Hip Abductor Muscle Strength _R	7.49 (6.20,9.89)	9.24 (7.32,12.70)	0.021*
Hip Abductor Muscle Strength _L	8.19 (6.66,9.36)	9.805 (8.21,11.46)	0.109
Avg. Hand Grip Strength _R	23.5 (19.45,34.95)	24 (19.17,34.72)	0.753
Avg. Hand Grip Strength _L	22.85 (19.1,31.22)	19.65 (13.4,29.41)	0.269

Table 4 shows the significant variables of impairment component of the ICF model. The median & IQR postoperative score of knee society score is KSS_KS 74 (IQR 70, 80),

KSS_FS 80 (IQR 72.5, 87.5), & KSS_TS 142 (IQR 131.75, 157.75) was improved from baseline pre-operative score of 43.5 (IQR 37.5, 50.25), 40 (IQR 40, 48.75), 130 (IQR 120, 133.75). Hip abductor muscle strength of right lower limb have shown a significant improvement in postoperative outcomes with the median & IQR value of 9.24 (IQR 7.32, 12.70) when compared to baseline preoperative value of 7.49 (IQR 6.20, 9.89). p value (<0.05).

Table 5

Comparison of Pre and Post operative functional outcomes on ICF (Activity limitation):

Variables	Preoperative Median (IQR P25,P75)	Postoperative Median (IQR P25,P75)	p value
WOMAC	40 (34,44.5)	11 (8,26)	0.002*
LEFS	33.5 (28.75,39.25)	50.5 (36.75,55.75)	0.002*
30 SECOND CST (in repetitions)	9(6.25,10.75)	11 (9,12)	0.125
SCT (in sec)	19.2 (16.7,28.72)	23 (18.45,31.22)	0.507
6MWT Distance Walked (in meters)	310.9 (267.9,328.4)	294 (175.82,325.75)	0.753
TUG (in sec)	12.35 (11.67,14.22)	13 (11.62,18.05)	0.753

Table 5 shows WOMAC and LEFS a significant change in postoperative outcomes from the baseline value of preoperative. Median score and IQR of WOMAC in postoperative is 11 (IQR 8, 26) from baseline preoperative score of 40 (IQR 34, 44.5). Median score and IQR of LEFS in postoperative is 50.5 (IQR 36.75, 55.75) from baseline preoperative score of 33.5 (IQR 28.75, 39.25). p value (<0.05)

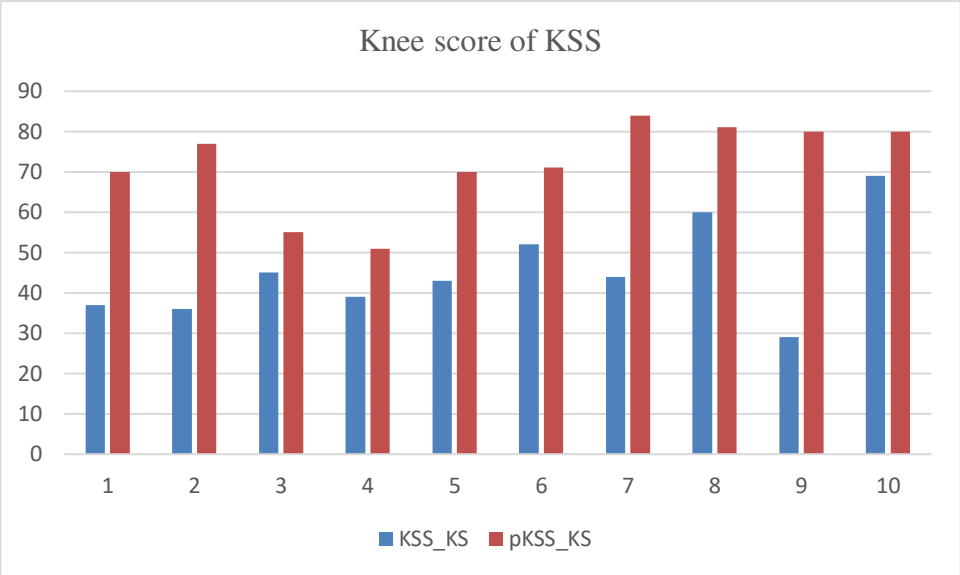
Table 6

Comparison of Pre and Post operative functional outcomes on ICF (Participation restriction):

Variables	Preoperative Median (IQR P25,P75)	Postoperative Median(IQR P25,P75)	P- value
LLFDI function Scaled Score	49.1 (47.47,52.11)	58.36 (54.14,60.03)	0.002*
LLFDI_Disability frequency Scaled Score	48.20 (44,51.71)	45.74 (43.53,46.77)	0.050
LLFDI_ Disability limitation Scaled Score	70.76 (67.75,73.64)	94.65 (83.44,100)	0.002*

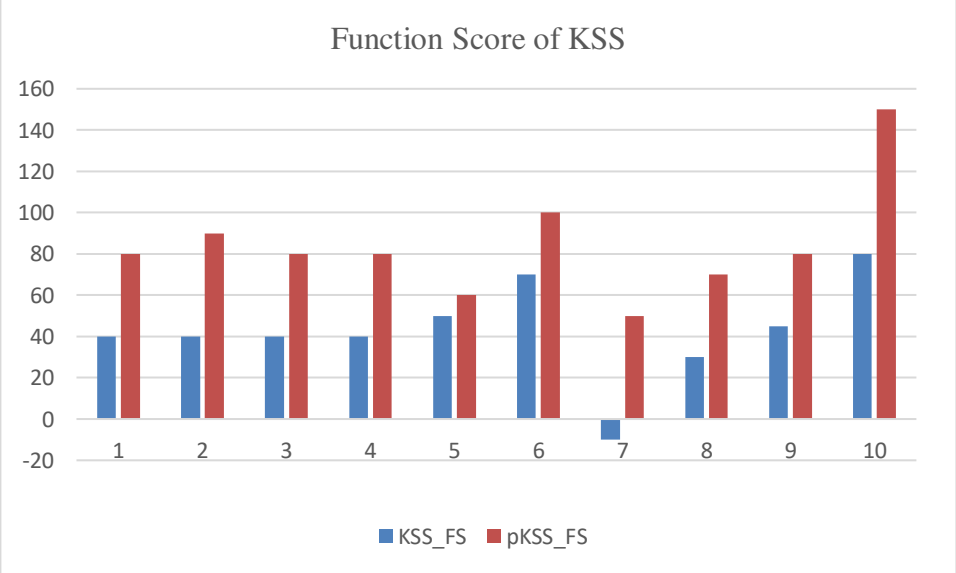
Table 6 shows the results of participation restriction of ICF model with significant change in LLFDI component of function and LLFDI disability/limitation. LLFDI scoring is calculated and a raw is scored. Raw scores are transformed to scaled scores of (0-100). Median score and IQR of LLFDI function component in postoperative was 58.36 (IQR 54.14, 60.03) from baseline preoperative of 49.1 (IQR 47.47, 52.11). Median score and IQR of LLFDI disability/limitation component in post operative was 94.65 (IQR 83.44, 100) from baseline preoperative of 70.76 (IQR 67.75, 73.64). p value (<0.05).

Graph 1: Knee score component of Knee Society Score



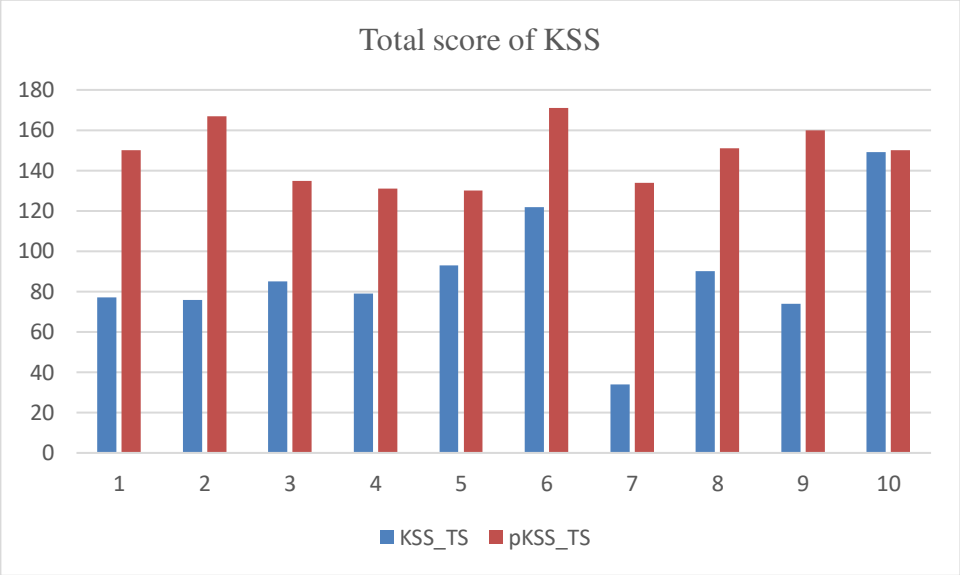
Graph 1 shows significant improvement in knee score (KS), a subscale of Knee society score (KSS) from preoperative to postoperative outcomes. Pain intensity was measured with knee score (KS), thus there was a significant reduction of pain in postoperative outcomes.

Graph 2: Function score component of Knee Society Score



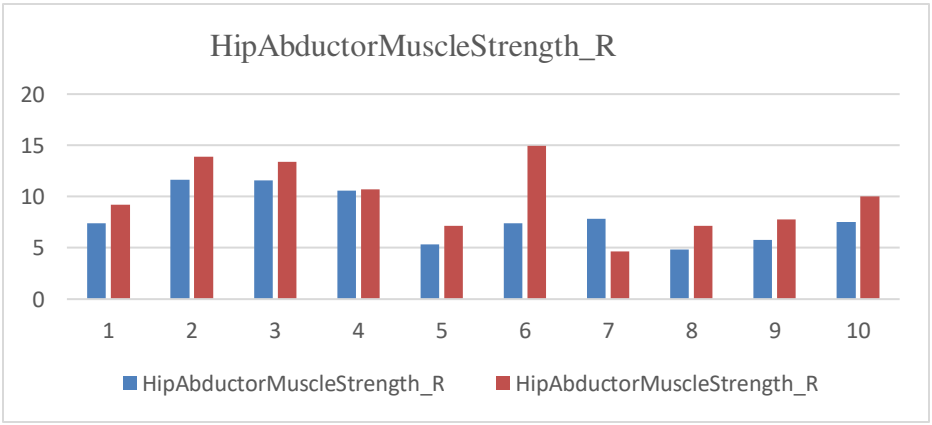
Graph 2 shows significant improvement in function score (FS), a subscale of knee society score (KSS) from preoperative to postoperative outcomes.

Graph 3: Total score of Knee Society Score



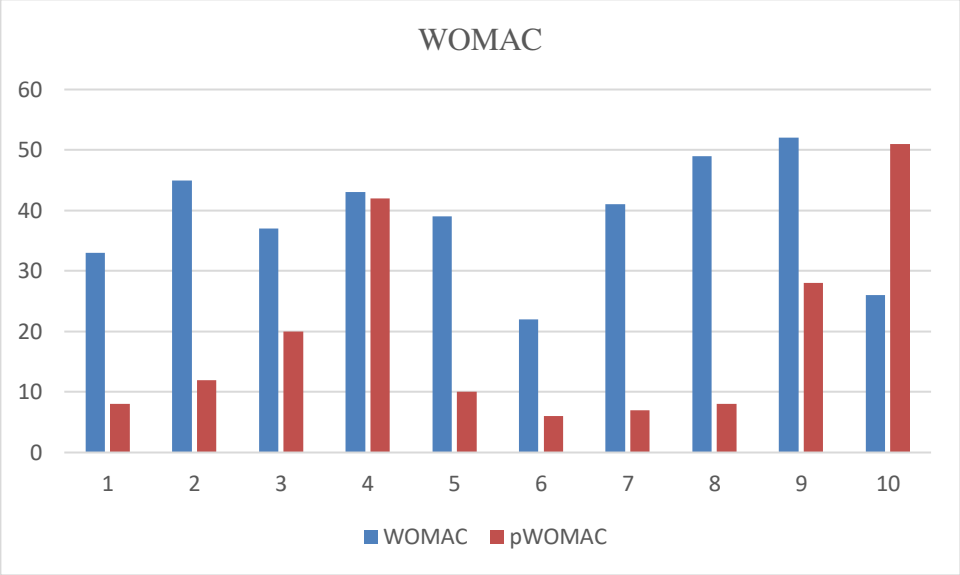
Graph 3 shows a combined score of knee score (KS) and function score (FS) and gives a value of total score (TS). The total score (TS) shows significant improvement from preoperative to postoperative outcomes. Therefore knee society scores (KSS) shows a significant improvement in postoperative outcomes following total knee arthroplasty.

Graph 4: Hip abductor muscle strength of right lower limb



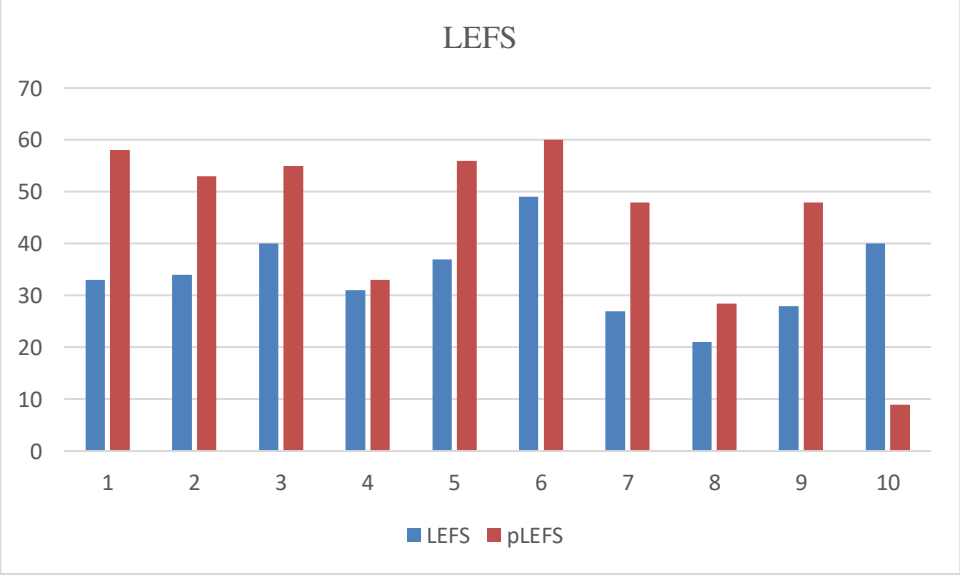
Graph 4 shows significant increased in muscle strength of right hip abductor at 3 months postoperative when compared to preoperative.

Graph 5: Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)



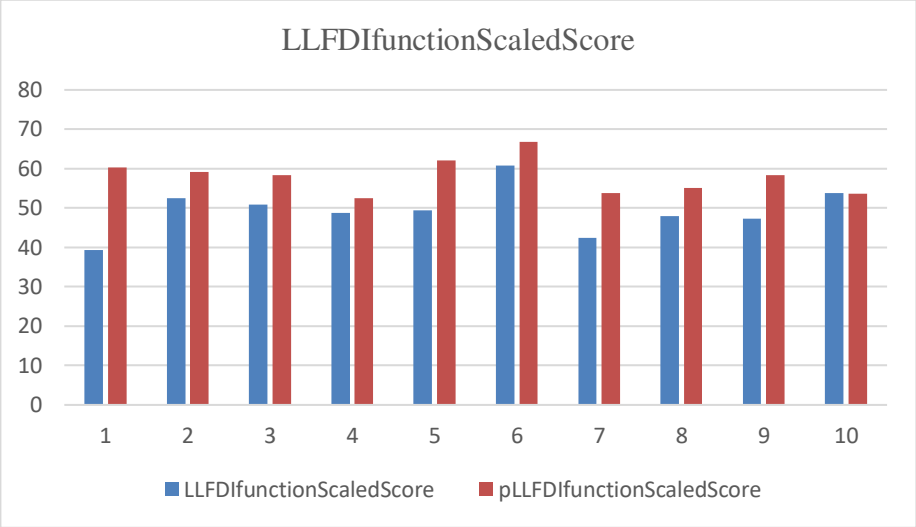
Graph 5 shows significant improvement in all the 3 domains of WOMAC- pain, stiffness and difficulty after total knee arthroplasty.

Graph 6: Lower Extremity Functional Scale (LEFS)



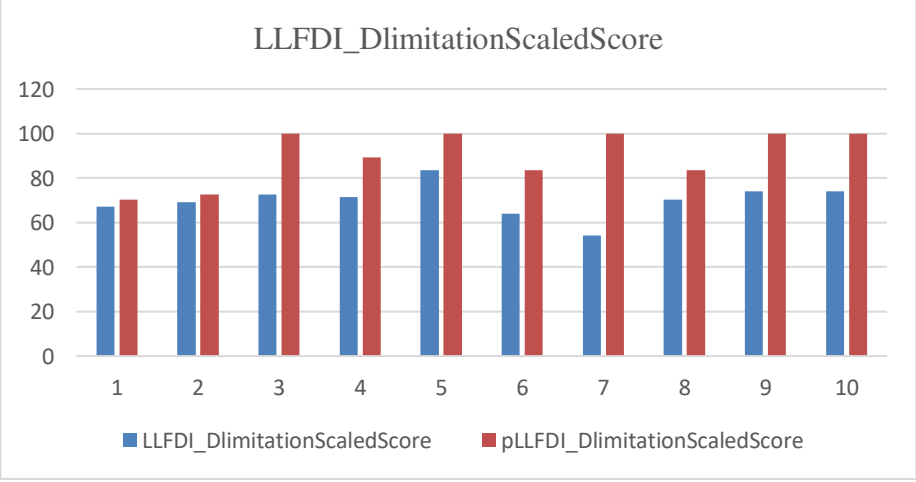
Graph 6 shows a significant improvement in the functional outcomes of lower limb after total knee arthroplasty.

Graph 7: Function component of Late Life Function and Disability Instrument



Graph 7 shows significant change in function subscales of LLFDI after total knee arthroplasty.

Graph 8: Disability (limitation component) of Late Life Function and Disability Instrument



Graph 8 shows significant change in disability (limitation component) of LLFDI after total knee arthroplasty.

6. DISCUSSION

Total knee arthroplasty is the common surgery performed for extreme pain and disability affecting the quality of life. There is a limited study on the use of ICF model for the functional outcomes of TKA. To the best of our knowledge there is no study done in Indian population that compare the functional outcomes of TKA based on ICF model. Aim of this study was to look for the functional outcomes before and after total knee arthroplasty on the ICF component of impairment level, activity limitation, and participation restriction.

Following total knee arthroplasty it is common for all patients to undergo impairments of the operated knee such as increased pain & swelling, decrease range of motion and further leads to limitation in activity and restriction to participate in the community life. Studies have found decrease in physical function in first one month of the surgery. (11)

International classification of functioning disability and health (ICF) is a framework that provides one language on the concepts of health, function and disability for clinicians worldwide. ICF domains make clinicians familiar about the tools use in regular clinical practice in different health conditions. Three key domains of ICF- impairment (body structure & function), activity limitation and participation restriction are closely related to physiotherapy. Total knee arthroplasty is the treatment of choice at end stage of osteoarthritis. (12)

The present study was a longitudinal cross-sectional study and compared the functional outcomes using ICF model following pre and post operative total knee arthroplasty. This

study has achieved statistical difference in the postoperative outcomes at 3 months of knee society scores (KSS).

Conaghan et al have studied 3 years of prospective study on clinical and ultrasonography predictors of joint replacement surgery and found knee pain intensity is the major factor for most patients to undergo knee arthroplasty. Knee pain intensity was measured with 0-100 mm VAS scale. Intensity of knee pain increases prior before surgery and this increase in pain is the reason where the surgeon decides to do the surgery. (48) At one month after the surgery self reported pain intensity has decreased slightly relative to preoperative level. (49,50) Intensity of knee pain gradually decreases over a period of month to slightly about more than a year, knee pain continue to decrease in the first couple of months where the rate of reduction is high. (49–51) In our study knee pain intensity was measured with KSS pain score (none - severe) and pain intensity improved significantly from 43.5 (IQR 37.5, 50.25) to 74 (IQR 70, 80), $p<0.05$ (table 4), at 3 months follow up when compared to preoperative.

Knee ROM is needed in day today daily activities and is an important aspect of outcome measures for undergoing total knee arthroplasty. Knee flexion of certain degrees are required for daily activities, 67° for swing phase of gait, 83° for climbing up the stairs, 90° for descending stairs and 93° for standing up from a chair. (51) Ritter & stringer have found preoperative flexion ROM is a important parameter for the prognosis of post operative knee flexion ROM. (52) Carvalho junior et al evaluated knee ROM at 6 months after TKA and concluded preoperative flexion range significantly influences the post operative TKA flexion ROM. (53) Studies have found significant improvement in knee ROM at 6 months follows up but in our study of 3 months follow up, knee ROM did not

show significant change. The probable reasons could be good preoperative knee range of motion.

Quadriceps strength in the involved limb before surgery have 20 % isometric strength deficit when compared with normal side and 40 % isometric strength deficit when compared with same age healthy persons. (49,54,55) After 1 month of TKA there is 50-60% of quadriceps strength reduction but over a period of 6 months quadriceps strength continues to improve gradually. (50,56) Farquhar et al have found that rate of improvement in quadriceps muscles strength in 1-4 months after surgery is rapid than in the period of 4-6 months. (57) Hip abductor strength is important in providing stability of the trunk and hip during walking and therefore it transfers the force from the lower limb to the pelvis and enhances the functional performance. Studies shows that hip abductor plays a vital role in knee joint function and weakness of these muscles will lead to altered biomechanical pattern of gait which was observed in OA knee. (58) In our study we did not find significant change of improvement in quadriceps strength. However hip abductor strength of right limb have showed significant change from 7.49 (IQR 6.20, 9.89) to 9.24 (IQR 7.32, 12.70), $p<0.05$ (table 4) at 3 months postoperative.

Hand grip strength is considered as a biomarker of multiple physiological systems. Grip strength plays an important role in prevention of injury. It is an important predictor in relation to functional outcomes, nutritional status, and mortality among elderly population. Studies have showed that grip strength declines with age, disability, and therefore it affects the quality of life. (59,60) In our study results showed no significant outcome difference in hand grip strength postoperatively though male subject had stronger grip strength than that of women.

Studies have found that WOMAC with combination of other self reported questionnaires such as KOOS and SF-36 are likely to identify patients with a risk of total knee arthroplasty. (61) WOMAC is also validated in use of measuring outcomes of clinical trials. (62) Physical function Subscale of WOMAC has found in TKA patient to be sensitive in detecting changes in activity limitation with MCID difference of 19 points on a 0-100 scale. (63) Studies found that major changes after TKR occurs in first 6 months and the mean improvements measured by WOMAC were very high. Our study supports previous study showing a significant change from 40 (IQR 34, 44.5) to 11 (IQR 8, 26), $p<0.05$ (table 5) at 3 months postoperative period.

Kennedy et al have used LEFS to assessed over a period of 1 year after total knee arthroplasty and found that greatest improvement occurs in the first 12 weeks after surgery and gradually improvement continued to occur in between 12 to 26 weeks. (64) Our study has found significant improvement from 33.5 (IQR 28.75, 39.25) to 50.5 (IQR 36.75, 55.75), $p<0.05$ (table 5) in postoperative outcomes at 3 months. Thus LEFS is a useful tool in TKA to measure the lower limb functional outcomes.

In our study performance based outcomes did not show a significant change in postoperative functional outcomes. In participation component of ICF, till date no study is done on total knee arthroplasty using late life function and disability instrument (LLFDI). However this study has found significant change in postoperative outcomes on two subscales of LLFDI, function and disability (limitation component). The preoperative LLFDI function score was 49.1 (IQR 47.47, 52.11) and at 3 months postoperative period it was 58.36 (IQR 54.14, 60.03), significant at $p<0.05$ (table 6). Similarly there was a significant difference in the LLFDI score of disability (limitation component), significant

at $p<0.05$ (Table 6). Thus LLFDI can apply for measuring participation component of ICF model in most health conditions.

7. CONCLUSION

To conclude, the present study found significant change at 3 months postoperative of knee society score (KSS) and right hip abductor muscle strength of impairment component. Similarly self-reported questionnaire (WOMAC and LEFS scale) of activity limitation component also find a significant change at 3 months postoperative. There was also a significant change on two domains of LLFDI (function component and limitation subscale of disability component) of participation restriction component at 3 months postoperative.

However the impairment component of ICF did not show a significant change in terms of range of motion, muscle strength of quadriceps and left hip abductor muscle strength, and hand grip strength. Performance based measures of activity limitation such as 30CST, SCT, 6MWT and TUG did not show a significant change at 3 months postoperative. Similarly LLFDI (frequency subscale of disability component) of participation restriction component did not show a significant change at 3 months postoperative. The insignificant results could be due to inadequate sample of subjects enrolled in the study.

Thus this study did not prove to find much difference in the functional outcomes using ICF model. However with a large number of subjects enrolled in future study, the ICF model can show a benefit and provide a clear functional profile of the subjects with the additional advantage of being able to describe the contextual factors.

8. LIMITATION AND RECOMMENDATION

This chapter explains about the study limitations and future recommendations which can be done.

Limitation:

- There are major limitation in this study with a fewer number of subjects enrolled in the study which could not conclude with a stronger results.
- Follow-up period of 3 months was very short due to which it may not have show a significant change in the functional outcomes.
- Regression analysis could not carried out due to low sample size.

Recommendation:

- Future studies need to be done as interventional study with a larger number of subjects enrolled to draw a meaningful conclusions.
- Evaluation of different knee prosthesis designs (single radius, multi-radius, & attune gradius) on functional outcomes using ICF model to know the better functional outcomes of one knee designs over the other.

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APPENDIX-1

CONSENT FORM

Study Title: Comprehensive evaluation of functional outcomes following total knee arthroplasty using international classification of function, disability and health (ICF) model.

Subject's Initials:____Subject's Name: _____

Date of Birth / Age: _____ Hospital no: _____

(i) I confirm that I have read and understood the information sheet dated____for the above study and have had the opportunity to ask questions. [ ]

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ]

(iii) I understand that, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s) [ ]

(v) I agree to take part in the above study. [ ]

Signature (or Thumb impression) of the Subject/Legally Acceptable

Date: __/_____/___

Signatory's Name:_____ Signature: _____

Signature of the Investigator: _____ Date: _____/_____/_____

Study Investigator's Name: _____

Signature or thumb impression of the Witness: _____

Date:___/_____/__

Name & Address of the Witness: _____

APPENDIX-2

PARTICIPANT INFORMATION SHEET

Study Title: Comprehensive evaluation of functional outcomes following total knee arthroplasty using international classification of function, disability and health (ICF) model.

Dear Sir/ Madam,

You are invited to participate in a study that aims to evaluate functional outcomes following total knee arthroplasty.

Why are we doing this study?

Osteoarthritis is a common degenerative disorder of the knee joint. Total knee arthroplasty is a surgical procedure done to replace the degenerated knee joint with metal prosthesis. The surgical procedure is now very common and routinely done to manage osteoarthritis. In this study we are attempting to evaluate the functional outcomes, which means, aspects like joint range, muscle strength, pain, grip strength, walking endurance and ability to participate in daily activities.

Description of the Research

You will be evaluated before surgery and at 3 months after total knee arthroplasty. A data form will be used to collect your demographic details. Standardized scales will be used to identify the functional performance and physical impairments. You may have to demonstrate certain activities like bending knee in lying position, walking, hand grip, stair climbing etc. You will have to give your responses to standard questions that will be asked from a questionnaire.

Can I withdraw from this study after it starts?

Yes. Your participation in this study is entirely voluntary and you are also free to withdraw from the study at any point of time. If you choose to withdraw from the study it will not affect your usual treatment at this hospital in any way. Your participation in this study will be appreciated.

What will happen if you develop any study related injury?

We don't anticipate any study related injury. All the assessment procedures are entirely safe and are performed regularly in physiotherapy.

Will you have to pay for the study?

Your assessment will be done completely free of cost.

How will you benefit from this study?

The evaluations done in this study will help us understand the improvements following total knee arthroplasty. In case at three months after surgery you have some physical difficulties, we will refer you for a rehabilitation program to a Physiotherapist. By participating in our study, you will contribute to the advancement of knowledge in this field.

Will your personal details be kept confidential?

All the information shared by the participant will remain strictly confidential at all times. Only the primary investigator and the co investigators will have access to your information. The results of this study will be published in a medical journal but your identification details will not be revealed in any presentation or publication.

For any further queries, please do contact:

Mr. C. Sanam Rana

Phone number: 9774608850, 8787478469

E-mail id: ranasanam13@gmail.com

APPENDIX-3

DATA COLLECTION FORM

Name:_____Age:_____Gender:_____Hospital No:_____Date: _

Address: Phone:_____Height (cms):_____Weight:_____kgs

Diagnosis: _____ BMI:_____ Education: Primary/Middle/

Secondary/Higher sec./Diploma/Graduate/Post graduate or higher

Co-morbidities: Diabetes/ Hypertension/ Obesity/ Dyslipidemia/ Others _____

Surgical data:

OA staging: Surgery approach:

(Kellgren Lawrence grade) Fixation technique:

Prosthesis type:

ASA classification: 1/ 2/ 3/ 4

Date of admission:_____Date of surgery:_____Date of discharge_____Length of stay:__days

Pre evaluation screening:

Karnofsky Functional Scale:_____*Attached as separate appendix*

Charlson Co-morbidity Index:_____*Attached as separate appendix*

Patient Health Questionnaire – 9 :_____*Attached as separate appendix*

Physical impairment evaluation:

1. Knee pain intensity: Knee Society Score (KSS) *(Attached as separate Appendix)*

Knee Score___Functional score:_____Total score:_____Grade: _____

2. Knee Range of Motion *(Circle operated side)*

Component	Right (in degrees)	Left (in degrees)
Knee Flexion		
Knee Extension		

3. Muscle strength evaluation *(Circle operated side)*

Component	Right (in Kg force)	Left (in Kg force)
Knee extensors		
Hip Abductors		

4. Hand grip strength *(At least 3 minutes rest between each trial)*

Component	Trial 1 (kgf)	Trial 2 (kgf)	Average (kgf)
Right			
Left			

Evaluation of activity limitation:

Patient reported activity limitation

5. Western Ontario McMaster University Osteoarthritis Index (WOMAC): *(Attached as separate Appendix)*

6. Lower Extremity Functional Scale (LEFS):_____*(Attached as separate Appendix)*

Performance based measure of activity limitation

7. 30 second Chair-Stand Test: _____

8. Stair Climb Test: _____

9. 6 Minute Walk Test

Component	HR (bpm)	BP (mm/Hg)	SpO2 (%)	Walking distance (in meters)
At rest				NA
After activity				

Lap distance: 15 meters Total distance walked =____meters

No of Laps:_____x 15

Last lap:_____meters

10. Timed Up and Go Test (TUG):_____seconds

Participation restriction measures:

11. Late Life Function and Disability Instrument (LLFDI): _____

OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Anna Benjamin Pulimood, M.B.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

July 12, 2018

Mr. Sanam Rana C
Student, Physiotherapy,
Department of PMR,
Christian Medical College,
Vellore – 632 004

Sub: **Fluid Research Grant: New Proposal:**
Comprehensive evaluation of functional outcomes of single-radius Vs multi-radius femoral types total knee arthroplasty using International Classification of Function, Disability and Health (ICF) – model.
Mr. Sanam Rana C MPT Orthopedics, I year Physiotherapy Unit, Mr. Andrew Babu MPT MIAP Sr. Reader & Head of Physiotherapy unit, PMR, Mr. Samuel Kirubakaran D, Mr. Pierre Edwin, Emp No. 39260, PMR Dr. Alfred Job Daniel, Orthopedics, Ms. Mahasampath Gowri, Biostatistics.

Ref: IRB Min. No. 11215 [OBSERV] dated 05.03.2018

Dear Mr. Sanam Rana C,

I enclose the following documents:-

1. Institutional Review Board approval 2. Agreement

Could you please sign the agreement and send it to Dr. Biju George, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board

Dr. BIJU GEORGE
MBBS., MD., DM.
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

Cc: Mr. Andrew Babu, Department of PMR, CMC

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
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Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

July 12, 2018

Mr. Sanam Rana C
Student, Physiotherapy,
Department of PMR,
Christian Medical College,
Vellore – 632 004

Sub: **Fluid Research Grant: New Proposal:**
Comprehensive evaluation of functional outcomes of single-radius Vs multi-radius femoral types total knee arthroplasty using International Classification of Function, Disability and Health (ICF) – model.
Mr. Sanam Rana C MPT Orthopedics, I year Physiotherapy Unit, Mr. Andrew Babu MPT MIAP Sr. Reader & Head of Physiotherapy unit, PMR, Mr. Samuel Kirubakaran D, Mr. Pierre Edwin, Emp No. 39260, PMR Dr. Alfred Job Daniel, Orthopedics, Ms. Mahasampath Gowri, Biostatistics.

Ref: IRB Min. No. 11215 [OBSERV] dated 05.03.2018

Dear Mr. Sanam Rana C,

The Institutional Review Board (**Blue**, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "Comprehensive evaluation of functional outcomes of single-radius Vs multi-radius femoral types total knee arthroplasty using International Classification of Function, Disability and Health (ICF) – model" on March 05, 2018.

The Committee reviewed the following documents:

1. IRB application format
2. Data Collection Form
3. Outcome Measures
4. Signature Pages
5. Patient Information Sheet and Consent form (Tamil, English, Hindi, Bengali, Telugu, Malayalam)
6. Cv's of Drs. D J Christopher, Richa M, Balamugesh, Dhivya, Tunny M.
7. No. of documents 1- 6

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
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Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

The following Institutional Review Board (Blue, Research & Ethics Committee) members were present at the meeting held on March 05th 2018 in the Jacob Chandy Hall, Paul Brand Building, Christian Medical College, Vellore 632 004.

Name	Qualification	Designation	Affiliation
Dr. Biju George	MBBS, MD, DM	Professor, Haematology, Research), Additional Vice Principal , Deputy Chairperson (Research Committee), Member Secretary (Ethics Committee), IRB, CMC, Vellore	Internal, Clinician
Dr. Mathew Joseph	MBBS, MCH	Professor, Neurosurgery, CMC, Vellore	Internal, Clinician
Dr. B. J. Prashantham	MA(Counseling Psychology), MA(Theology), Dr. Min(Clinical Counseling)	Chairperson, Ethics Committee, IRB, Director, Christian Counseling Centre, Vellore	External, Social Scientist
Dr. Sowmya Sathyendra	MBBS, MD (Gen. Medicine)	Professor, Medicine III, CMC, Vellore	Internal, Clinician
Dr. Thomas V Paul	MBBS, MD, DNB, PhD	Professor, Endocrinology, CMC, Vellore	Internal, Clinician
Mr. C. Sampath	BSc, BL	Advocate, Vellore	External, Legal Expert
Dr. Jayaprakash Muliyil	BSc, MBBS, MD, MPH, Dr PH (Epid), DMHC	Retired Professor, CMC, Vellore	External, Scientist &Epidemiologist
Ms. Grace Rebekha	M.Sc., (Biostatistics)	Lecturer, Biostatistics, CMC, Vellore	Internal, Statistician
Dr SnehaVarkki	MBBS, DCH, DNB	Professor, Paediatrics, CMC, Vellore	Internal, Clinician
Dr. Shyam Kumar NK	MBBS, DMRD, DNB, FRCR, FRANZCR	Professor, Radiology, CMC, Vellore	Internal, Clinician
Mrs. Pattabiraman	BSc, DSSA	Social Worker, Vellore	External, Lay Person

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
Tel: 0416 – 2284294, 2284202 Fax: 0416 – 2262788, 2284481 E-mail: research@cmcvellore.ac.in

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Anna Benjamin Pulimood, M.B.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

Mrs. Nirmala Margaret	MSc Nursing	Professor, Medical Surgical Nursing, CMC, Vellore	Internal, Nurse
Dr. John Antony Jude Prakash	MBBS, MD	Professor, Clinical Microbiology, CMC, Vellore.	Internal, Clinician.
Dr. AjithSivadasan	MD, DM	Professor, Neurological Sciences, CMC, Vellore	Internal, Clinician

We approve the project to be conducted as presented.

The Institutional Ethics Committee expects to be informed about the progress of the project, any **adverse events** occurring in the course of the project, any **amendments in the protocol and the patient information / informed consent.** On completion of the study you are expected to submit a copy of the **final report.** Respective forms can be downloaded from the following link: http://172.16.23.136/Research/IRB_Polices.html in the CMC Intranet and in the CMC website link address: http://www.cmch-vellore.edu/static/research/Index.html.

Kindly provide the total number of patients enrolled in your study and the total number of Withdrawals for the study entitled: "Comprehensive evaluation of functional outcomes of single-radius Vs multi-radius femoral types total knee arthroplasty using International Classification of Function, Disability and Health (ICF) – model" on a monthly basis. Please send copies of this to the Research Office(research@cmcvellore.ac.in).

Fluid Grant Allocation:

A sum of 25,000/- INR (Rupees Twenty Five thousand Only) will be granted for 24 months.

Yours sincerely,

Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board

Dr. BIJU GEORGE
MBBS., MD., DM.
SECRETARY (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

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